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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/747,524	12/19/2000	Y. Tom Tang	PC-0022 CIP	9999

7590 05/31/2002

LEGAL DEPARTMENT
INCYTE GENOMICS, INC.
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EXAMINER

HILL, MYRON G

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 05/31/2002

9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/747,524

Applicant(s)

TANG ET AL.

Examiner

Myron G. Hill

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) 7-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 December 2000 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4. 6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I (including the selection of SEQ ID#1 for examination) in Paper No. 9 (4/15/02) is acknowledged. The traversal is on the ground(s) that it would not be a burden to search the additional inventive groups II (claim 6) and V (claims 13 and 14). The method of using the cDNA in claim 6 (Group II) will be rejoined. The traversal is not found persuasive for group V because it would be an additional burden to search for the protein since it requires more than just a sequence search. The search would have to encompass looking for proteins that are described as similar- proteins of the same size, proteins obtained from the same cell types, proteins that have similar functions, and proteins that are associated with similar conditions. The scope of the search required would not be coextensive. Applicant is further reminded that they should amend the claims to not include any of subject matter not encompassed by the elected group and SEQ ID#. Parts b and c of claim 2 will be searched only to the extent that they read on the elected sequence.

The requirement is still deemed proper and is therefore made FINAL.

The claims under consideration in this office action are 1- 5 and 6. Claims 7- 20 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1- 6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 1 the metes and bounds of of the cDNA are not clear. Does the cDNA encode a protein having residues in addition to SEQ ID#1? Do claims 1 and 2 consist of the recited sequences or do they comprise the recited sequences?

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim1- 6 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention.

Applicant asserts that the DNA and protein are useful in the diagnosis and treatment of disorders associated with inflammation (page 3, lines 7- 9). Figure 3A shows that this DNA is expressed in many tissue types and Figure 3B shows that it is expressed in samples from several lymphoid tissues, most with cancer related conditions. However, one skilled in the art would have reason to doubt the usefulness of the DNA (or protein) for diagnosis or treatment of diseases or disorders associated with

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inflammation and immune response (list in specification page 19, lines 4- 22). There is no guidance as to which diseases or disorders from this long list that there is a particular association because there is no showing in the specification that links a particular disease state to a particular presence of the cDNA. There is no teaching in the specification on the sensitivity or specificity of the diagnostic indication (presence of cDNA). It is not clear if there would be false positives or negatives associated with this test. Page 19 line 23 indicates that conditions are caused by increased expression of the protein but it is not clear that this can be differentiated from normal cells or particular diseases or states of disease/ disorder progression. Figure 3B does not indicate that the detection of the cDNA is from normal or increased expression situations or that it can determine a specific disease or condition. There are no working examples of diagnosis or treatment.

Considering the long list of possible diseases, drawn to many different populations having conditions with different symptoms and disease endpoints, the amount of work needed to establish the association/ correlation of a particular disease state, the very general nature of the teachings in the specification, and the lack of working examples that show the ability to specifically diagnosis a specific condition or treat a condition in a specific way, it is considered to require undue experimentation to use the invention.

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Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Myron G. Hill whose telephone number is 703-308-4521. The examiner can normally be reached on 9am-6pm Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4247. The fax phone number for the organization where this application or proceeding is assigned is 703-308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Myron G. Hill
Patent Examiner
May 30, 2002

Mary Mosher
MARY E. MOSHER
PRIMARY EXAMINER
GROUP 1800
1600